ISRCTN10688342 https://doi.org/10.1186/ISRCTN10688342

Investigation of the effectiveness and cost-effectiveness of the 'Girls Active' intervention

Submission date
06/01/2015

Recruitment status
No longer recruiting

Registration date
12/01/2015

Overall study status
Completed

Last Edited
09/02/2023

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Young people in the UK are not as physically active as they should be. Girls tend to do less physical activity than boys, especially as they progress to secondary school. To address this and encourage girls to be more physically active both inside and outside of school, the Youth Sport Trust has developed a programme called ‘Girls Active’. ‘Girls Active’ provides training, resources and support for teachers to give them the skills to change the way they deliver physical activity, sport and PE, and encourages girls themselves to act as positive role models for others. We want to evaluate how effective ‘Girls Active’ is at increasing physical activity and whether the programme is value for money.

Who can participate?
We will recruit 20 schools in Leicester, Leicestershire and Rutland. Within these schools all girls aged 11-14 years will be eligible to take part, but only 80 girls in each school will be randomly selected to participate in the evaluation.

What does the study involve?
Half of the schools will receive ‘Girls Active’ and the other half will carry on with their usual practice until the end of the study. A team of researchers (with current enhanced DBS clearance) will visit each school to complete the measurements. The girls’ physical activity levels will be measured using a wrist worn physical activity monitor for 7 days. Participating girls will complete questionnaires about their lifestyle and feelings towards physical activity, sport and PE. They will also have physical measurements taken (height, weight and % body fat). We will also ask the teachers to complete a questionnaire about their school’s facilities, PE classes and lunchtime and after school activity sessions. We will carry out all of these measurements just before the schools receive the 'Girls Active' project (baseline) and then again 7 and 14 months after the first measurements (follow-up).

What are the possible benefits and risks of participating?
If we show that ‘Girls Active’ increases physical activity levels in girls, it could be made available to other secondary schools in the UK. It could lead to teenage girls becoming more active,

healthier and staying active when they are adults. Any potential risk of participating in this evaluation will be minimised by only using female researchers to take the physical measurements and not showing the participating girls their values.

Where is the study run from?
Diabetes Research Centre, Leicester General Hospital (UK).

When is the study starting and how long is it expected to run for?
From February 2015 to January 2017.

Who is funding the study?
National Institute for Health Research (UK).

Who is the main contact?
Dr Deirdre Harrington (dh204@leicester.ac.uk)
Mrs Kyla Harrington (kyla.harrington@uhl-tr.nhs.uk)

Contact information

Type(s)
Scientific

Contact name
Dr Deirdre Harrington

ORCID ID
https://orcid.org/0000-0003-0278-6812

Contact details
Diabetes Research Centre
Univesity of Leicester
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW
+44 (0)116 258 8630
dh204@leicester.ac.uk

Type(s)
Public

Contact name
Mrs Kyla Harrington

Contact details
Diabetes Research Centre
Univesity of Leicester
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

+44 (0)1162584180
kyla.harrington@uhl-tr.nhs.uk

Additional identifiers

Study information

Scientific Title
A cluster randomised controlled trial to investigate the effectiveness and cost-effectiveness of the 'Girls Active' intervention

Acronym
Girls Active

Study objectives
Despite the health benefits of physical activity, data from the UK suggests that a large proportion of adolescents do not meet the recommended levels of moderate-to-vigorous physical activity (MVPA). This is particularly evident in girls, who are less active than boys across all ages and display a faster rate of decline in physical activity throughout adolescence. Furthermore, a large drop in the proportion of girls meeting MVPA guidelines occurs during and following the transition to secondary school (age 11+). 'Girls Active' has been developed by the Youth Sport Trust to target the lower participation rates observed in adolescent girls, specifically aged 11-14 years. This study will evaluate the effectiveness and cost-effectiveness of the 'Girls Active' intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Medicine and Biological Sciences Research Ethics Committee, University of Leicester, 12/12/2014, ref: mlh31-fa761

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Physical activity

Interventions
This study will recruit 20 schools within Leicester, Leicestershire and Rutland. At each school a random sample of ~80 Key Stage 3 girls (aged 11-14 years) will be selected to take part in the evaluation measures. Baseline visit will record height, weight and percentage body fat. Participants will be asked to complete lifestyle questionnaires and wear a wrist worn accelerometer for the 8 days following the study visit.

Once the baseline measurements are complete in all 20 schools an independent statistician will randomise half of the schools to the intervention condition (to receive Girls Active) and half to usual care (the control) condition based on school size and proportion of BME pupils.

The measurement session described above will then be repeated at 7 and 14 months.

Process evaluation will also be undertaken with lead teachers and the girls involved in the Girls Active intervention throughout the length of the evaluation. This will involve asking teachers to complete questionnaires on school physical activity, sport and PE provision, and tracking Girls Active delivery.

Intervention Type
Behavioural

Primary outcome(s)
A significant difference in mean minutes of moderate to vigorous activity between the intervention and the control group, measured by accelerometer at 14 months after baseline assessment.

Key secondary outcome(s)
1. A change in the following outcomes 7 and 14 months after baseline assessment:
1.1. Increase in objectively measured total volume of physical activity (accelerometer counts /days)
1.2. Increase in the proportion of girls meeting MVPA guidelines (objectively measured)
1.3. Increase in objectively measured MVPA at 7 months
1.4. Reduction in time spent sedentary (objectively measured and self-reported)
1.5. Reduction in measures of adiposity (body mass index, percentile, percent body fat)
1.6. Improvement in psychological factors that may mediate physical activity participation
2. A full cost effectiveness and cost-consequence analysis of the 'Girls Active' programme
3. A process evaluation of intervention implementation

Completion date
31/01/2017

Eligibility

Key inclusion criteria
School inclusion criteria:
1. Government-funded secondary school within Leicester, Leicestershire and Rutland
2. Schools with at least 80 Key Stage 3 girls

Pupil inclusion criteria:
1. Key Stage 3 girls (must be aged 11, 12, 13 or 14 years)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 Years

Upper age limit
14 Years

Sex
Female

Total final enrolment
1752

Key exclusion criteria
School exclusion criteria:
1. Private or independent schools and designated special needs schools
2. Schools that do not have any Key Stage 3 pupils

Pupil exclusion criteria:
1. Girls outside of the targeted age range
2. Parent opt-out consent returned

Date of first enrolment
01/02/2015

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Diabetes Research Centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
The University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/04/2018		Yes	No
Results article		16/08/2019	19/08/2019	Yes	No
Results article		01/02/2019	09/02/2023	Yes	No
Protocol article		04/06/2015		Yes	No
Other publications	process evaluation	29/08/2019	30/08/2019	Yes	No